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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,514	02/11/2004	Kerry Zang	073275.0163	5263
5073	7590	11/04/2009		
BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			EXAMINER MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	
			NOTIFICATION DATE	DELIVERY MODE
			11/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/777,514

Applicant(s)

ZANG ET AL.

Examiner

CHERYL MILLER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-44, 46-57, 62, 63 and 65-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44, 46-57, 62, 63, and 65-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 40-44, 46-57, 62, 63, and 65-70 have been considered but are moot in view of the new ground(s) of rejection.

Specification

The amendment filed April 28, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: each new recitation of substantially. Although applicant appears to have support for constant thread height and pitch, applicant does not appear to have support for the term "substantially" constant.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-44, 46-57, 62-63, and 65-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 40, 44, 46, 48, 55, 67, and 70 each recite, “a *substantially* constant” thread height or pitch. Although applicant seems to have support for a constant thread height or pitch (support provided in original claim by applicant in response), applicant does not have support for the term “*substantially*” which broadens the dimension to a range such that adjacent threads may have slightly different dimensions. It is unclear whether or not “substantially constant” covers the figures 1a, 1b, wherein there seemingly is a large tolerance since a taper is seen in the figures. If indeed “substantially constant” is shown in fig. 1a, 1b, then slight tapers in the prior art (as shown in the applicants figures) may also be considered “substantially constant”. Claims 41-43, 47, 49-54, 56-57, 62-63, 65-66, 68-69, and 71-72 depend upon the above claims and inherit all problems associated therewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 40-42, 44, 47, 50, 52-57, 62, 63, 66, and 70-72 are rejected under 35

U.S.C. 102(b) as being anticipated by Simon et al. (US 5,951,560, cited previously). Simon discloses an implant (see figs.1-5) comprising a headless body *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (13), second end (12), at least one continuous uninterrupted thread (14) having a flat crest (16), spanning from the first end to

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the second end and having a substantially constant thread height (see fig.2, is considered *substantially* constant, there is a small taper, but appears to be just as tapered or "*substantially* constant" as applicants show their threads in fig.1a, 1b of the present application), a recessed engagement (22), a tapered exterior surface from one end to the other (see fig.2), and leading and trailing flanks (17, 18; fig.5) with narrowing clearance therebetween. Simon shows a hex, cylindrical recess, countersunk and bore in fig.2.

Claims 40-42, 44, 50, 52-57, 63, 66, 70, and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Pavlov et al. (US 7,608,105 B2). Pavlov discloses an implant (see fig.1) comprising a headless body *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (26), second end (24), *at least one* continuous uninterrupted thread (*plurality* of individual threads, each one uninterrupted seen in fig.1) having a flat crest (peak of thread, seen in fig.1, 10), spanning from the first end to the second end and having a substantially constant thread height (shown as constant height in fig.1), a recessed engagement (34), a tapered exterior surface from one end to the other (see fig.1, 5), and leading and trailing flanks (fig.1,5) with narrowing clearance therebetween. Pavlov discloses a hex, cylinder and bore (col.4, lines 31-35).

Claims 40, 55, and 70-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosan, Sr. (US 3,726,180). Rosan discloses an implant (see fig.1) comprising a headless body (10) *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (top), second end (bottom), at least one continuous uninterrupted thread (12) having a flat crest (peak of thread, seen in fig.1), spanning from the first end to the second end and having a substantially constant thread height (shown as constant height in fig.1), a recessed engagement

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(bore 13), a tapered exterior surface from a first diameter to a second diameter (length of 12a; bottom portion of 10), and leading and trailing flanks with narrowing clearance therebetween (see fig.1).

Claims 40-44, 47, 50, 52-57, 62-63, 66, 70, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Visotsky et al. (US 2002/0038123 A1). Visotsky discloses an implant (see fig.1, 2a) comprising a headless body *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (30), second end (20), *at least one* continuous uninterrupted thread (*plurality* of individual threads 41, each one being uninterrupted seen in fig.1) having a flat crest (peak of thread, seen in fig.1, 4b), spanning from the first end to the second end and having a substantially constant thread height (shown as constant height in fig.1), a recessed engagement (31), a tapered exterior surface from one end to the other (see fig.1, 2), and leading and trailing flanks (fig.4b) with narrowing clearance therebetween. Visotsky discloses a hex, cylinder and bore (P0007).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Visotsky et al. (US 2002/0038123 A1). Visotsky discloses an implant (see fig.1, 2a) comprising a headless body *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (30), second end (20), *at least one* continuous uninterrupted thread (*plurality* of individual

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threads 41, each one being uninterrupted seen in fig.1) having a flat crest (peak of thread, seen in fig.1, 4b), spanning from the first end to the second end and having a substantially constant thread height (shown as constant height in fig.1), a recessed engagement (31), a tapered exterior surface from one end to the other (see fig.1, 2), and leading and trailing flanks (fig.4b) with narrowing clearance therebetween. Visotsky discloses a hex, cylinder and bore (P0007).

Visotsky discloses an implant and method of implantation substantially as claimed. Visotsky discloses insertion of the implant into bone where realignment is necessary (abstract, P0001, P0023), however does not specifically disclose placement into the sinus tarsi. It would have been obvious to one having ordinary skill in the art at the time the invention was made to implant the implant of Visotsky's into the sinus tarsi, since the sinus tarsi is a bony space in the body sometimes in need of realignment (which has been disclosed to be the purpose of Visotsky's implant).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755.

The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738